# In the United States Court of Federal Claims Office of special masters No. 21-1774V

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## RULING ON ONSET<sup>1</sup>

On August 30, 2021, Felicia Williams filed a *pro se* petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"). Petitioner alleges that she suffered a shoulder injury related to vaccine administration ("SIRVA") in her left shoulder as a result of an influenza ("flu") vaccine she received on October 23, 2019. Petition (ECF No. 1) at 1.

A dispute has arisen between the parties as to whether Petitioner can satisfy the onset element of a Table SIRVA claim. For the reasons discussed below, I find that Petitioner can.

<sup>&</sup>lt;sup>1</sup> Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available to the public in its current form. *Id*.

<sup>&</sup>lt;sup>2</sup> The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. §§ 300aa-10–34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

#### I. Relevant Procedural History

As noted above, this case was initiated in August 2021 and was originally assigned to a different special master before being assigned to me on September 9, 2021. It began as a *pro se* matter, but Petitioner retained counsel in January 2022.

Petitioner filed the relevant medical records with the Statement of Completion filed on October 20, 2022. (ECF No. 36). After efforts to settle the case were unsuccessful, Respondent filed a status report providing an informal assessment of the claim. (ECF No. 38). On February 14, 2023, I issued an order directing Petitioner to file a brief addressing the issue of onset. *See* non-PDF Order, dated Feb. 14, 2023. Petitioner's Brief Regarding Onset was filed on March 9, 2023. Brief, dated Mar. 9, 2023. (ECF No. 39) ("Br."). Respondent filed his Response on March 31, 2023. Response, dated Mar. 31, 2023. (ECF No. 40) ("Resp."). The claim is now ripe for resolution.

### II. Findings of Fact Regarding Onset

#### A. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement<sup>3</sup>, a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

To establish a Table SIRVA, a petitioner must satisfy the four QAI requirements. See 42 C.F.R. § 100.3(a)(XIV)(b) (Table entry for SIRVA following influenza vaccine; 42 C.F.R. § 100.3(c)(10)(i-iv). Specifically, Petitioner must demonstrate that there is no history of prior shoulder pathology that would explain her injury, that the onset of her left shoulder pain occurred within the specified time frame, that the filed medical records and affidavits support that Petitioner's shoulder pain and reduced range of motion were limited to the left shoulder, and that there is no evidence of any other condition or abnormality that represents an alternative cause. Id.

A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied

<sup>&</sup>lt;sup>3</sup> In summary, a petitioner must establish that she received a vaccine covered by the Program, administered in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See § 11(c)(1)(A)(B)(D)(E).

to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at \*19. And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistences between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] ... did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare not only the medical records and testimony, but also all other "relevant and reliable evidence contained in the record." *La Londe*,

110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); see also Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational). And although later oral testimony that conflicts with medical records is less reliable as a general matter, it is appropriate for a special master to credit a petitioner's lay testimony where it does not conflict with the contemporaneous records. Kirby, 997 F.3d at 1382–84.

#### B. Analysis

I have fully reviewed the evidence, including all medical records and affidavits, Respondent's Rule 4(c) Report, and the parties' briefs. I find most relevant the following:

- On November 26, 2018, Petitioner met with orthopedist, Mostafa El Dafrawy, M.D., for a preoperative consultation. Ex. 8 at 46–47. Petitioner exhibited "generalized weakness of her left upper extremity and sustained bilateral clonus in both lower extremities." *Id.* at 46. Dr. Dafrawy also noted that Petitioner had a "...past medical history significant for fibromyalgia, anxiety, depression, lumbar spinal stenosis, and flatback syndrome..." Ex. 8 at 48.
- On August 23, 2019, Petitioner left a message with her primary care provider ("PCP"), Ying Du, M.D., informing Dr. Du that "... she has been in pain for about 2 weeks (all over her body) ..." Ex. 23 at 14–15.
- On October 23, 2019, Petitioner received a trivalent influenza vaccination in her left deltoid from her PCP, Dr. Du. Ex. 2 at 4. Petitioner also at this time received a Tetanus and diphtheria vaccine in her right arm. Ex. 3 at 31.
- On January 22, 2020 (now almost three months post-vaccination), Petitioner saw Dr. Du with her chief complaint being fibromyalgia. Petitioner also reported, however, that her "left arm and shoulder have been hurting for a couple of months..." Ex. 3 at 39. Dr. Du noted decreased range of motion. *Id.* at 40. Dr. Du suggested X-ray and physical therapy. *Id.* at 40–41. The X-ray showed no signs of fracture or dislocation, and there were no significant degenerative changes. *Id.* at 42.
- On February 7, 2020, Petitioner went to physical therapy at Barnes Jewish St. Peters Hospital. Ex. 14 at 42. The Petitioner reported that the pain she was experiencing was "noticed after flu shoulder [sic]." *Id.* She also identified the starting date as "3 months" (presumably meaning it began around three months ago). *Id.* Along with noting left shoulder pain, Petitioner complained of pain from her pectoral to her neck and the back of

her shoulder. *Id.* She also complained of numbness and tingling going down her arm to her thumb." *Id.* 

- On March 2, 2020, Petitioner saw orthopedic surgeon, Richard Hulsey, M.D., for an initial consultation regarding her left shoulder. Ex. 5 at 4. Petitioner noted that she "...developed shoulder pain about four months ago after getting a flu shot in the left deltoid." *Id.* She reported that she had seen little improvement from physical therapy and that she was suffering from loss of motion, tingling in her thumb, and soreness extending into her neck. *Id.* Dr. Hulsey noted that Petitioner had no prior problems with her shoulder. *Id.* After an examination, Dr. Hulsey noted that Petitioner's left shoulder did not have atrophy or deformity but that her active and passive range of motion in her left shoulder was limited to slightly beyond 90 degrees. *Id.* at 4–5. Petitioner's left shoulder external rotation was only about 40 degrees with an abducted arm. *Id.*
- On May 1, 2020, Petitioner again saw Dr. Hulsey for a follow up appointment. Ex. 5 at 6. Dr Hulsey examined Petitioner and noted that her range of motion (active and passive) was about the same at 95–100 degrees with a firm endpoint. *Id.* Dr. Hulsey also noted that Petitioner had an external rotation of 20 degrees with the arm at her side and 40 degrees with the arm abducted. *Id.* Dr. Hulsey found no atrophy or deformity. *Id.* Dr. Hulsey noted in his recommendation that "I do not have any specific mechanism for the flu shot to cause the adhesive capsulitis, but it began soon after the injection." *Id.* Dr. Hulsey then recommended an MRI. *Id.*
- On May 4, 2020, the results of Petitioner's MRI showed mild to moderate rotator cuff tendinopathy that becomes more severe in the far anterior supraspinatus. Ex. 4 at 2. The MRI also revealed mild arthritic changes, and a suggestion of mild subacromial/subdeltoid bursitis. *Id.* The MRI report also mentioned shoulder pain and "pain after a flu shot." *Id.*
- There is a subsequent large gap in the treatment history. On August 31, 2022, Petitioner went to Shannon Potter, M.D., for an annual gynecological exam. Ex. 20 at 5. Dr. Potter noted that all of Petitioner's medical problems had become exacerbated after getting Covid sometime in March. *Id*.
- On May 5, 2022, Petitioner went to Barnes Jewish St. Peters Hospital for physical therapy. It was noted that Petitioner had increasing difficulty with her shoulder since having Covid (but mentions no exact dates for when she was so diagnosed). Ex. 15 at 14. It is further noted that these problems have been occurring for a "few years" but have been exacerbated by Covid.

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- Prior to filing her *pro se* Petition in the United States Court of Federal Claims, Petitioner filed a *pro se* Complaint in the United States District Court for the Eastern District of Missouri which was later dismissed for lack of subject matter jurisdiction. Br. at 5. However, Petitioner included a hand-written description of her injury with her initial Complaint—noting that for many years she had declined getting the flu vaccine, but in October 2019, she agreed to get one because she was already getting the Td vaccine. Affidavit of Felicia Williams at ¶ 11. Petitioner further recounts that she was in pain from the moment she received the vaccine. *Id*.
- Petitioner also notes that her right arm (in which she received the Td vaccine) was only slightly sore post-vaccination and resolved within a few days, but that her left arm felt numb, the pain was aching, and continued to get worse. Affidavit of Felicia Williams at ¶¶ 5–6. Petitioner called Dr. Du's office to schedule an appointment but was told that the pain may take up to 2-3 weeks to resolve. *Id.* at ¶ 7. Petitioner called and attempted to make an appointment after the pain became progressively worse but could not get an appointment until after Christmas. *Id.* at ¶¶ 8–9. Petitioner recounts telling Dr. Du during her appointment that her left shoulder pain began immediately after receipt of the flu vaccine. *Id.* at 10.
- Petitioner's husband submitted an affidavit in which he recounts that Petitioner's arm began hurting immediately after receiving the flu shot and the pain grew worse over the next several months prompting treatment. Affidavit of Richard Williams at ¶¶ 4–6.

Respondent argues that because Petitioner waited almost three months to seek help, her exact recollection as to onset could be questioned. Resp. at 4. However, claimants may often delay treatment for SIRVA injuries (and I have repeatedly found that such delay is ultimately more relevant to the severity of the injury, and thus pertains to the damages to be awarded). Respondent also focuses on the absence of any definitive statement that the injury occurred within 48 hours of the injection. While the exact phrase "within 48 hours" is absent, there are repeated mentions of the shoulder pain starting *post vaccination* within Petitioner's medical records. Ex. 5 at 4. The specificity of the onset date may not be evident from this record, but the overall weight of these items of proof supports a Table onset (even if not robustly).

Petitioner has also supported Table onset with witness statements. Although Petitioner waited several months before reporting her shoulder pain following the flu shot, she points to affidavits stating that she waited until the symptoms continued to worsen before seeking medical treatment. Affidavit of Felicia Williams at  $\P$  6; Affidavit of Richard Williams at  $\P$  4–6. According to her affidavit, Petitioner was initially told to wait a few weeks, and then also had to wait until after Christmas to receive and appointment. Affidavit of Felicia Williams at  $\P$  7–9.

Respondent further argues that Petitioner's preexisting conditions may also cast doubt as to whether this is some new novel pain or a continuation of past symptoms. Resp. at 5; Ex. 8 at

46–47; Ex. 23 at 14–15. Respondent points to the Petitioner having Covid at some point and reports that this might have exacerbated all her symptoms. Ex. 15 at 14; Ex. 20 at 5. Her infection with Covid would, according to the gynecological report, have been during sometime in March. Ex. 20 at 5. These issues likely require more factual development. In particular, I cannot at this time conclude that Petitioner had no preexisting symptoms or condition unrelated to her SIRVA. By contrast, whether Petitioner's intervening Covid diagnosis played a role in exacerbating her injury is a damages-oriented analysis.

I therefore find that Petitioner's onset likely occurred within 48 hours of vaccination, but defer determining the other issues the parties have raised. I will provide the parties a short period of time to attempt settlement of this case in light of my findings—but if they cannot do so in light of the litigation risks they both face, I will set a schedule for evidentiary input on the remaining aspects of the case.

#### **CONCLUSION**

The record evidence preponderantly supports the determination that Petitioner's SIRVA onset occurred within 48 hours of vaccination. The parties will attempt settlement, and shall file status reports on July 31, 2023, and August 31, 2023. If the matter is not resolved by the latter date (or if the parties determine prior to that time that settlement is not possible), they shall request a status conference.

IT IS SO ORDERED.

/s/ Brian H. Corcoran Brian H. Corcoran Chief Special Master